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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,131	02/16/2001	Adrian Gilbert	60623-A/JPW/GJG/CSN	5640

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EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/30/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/788,131

Applicant(s)

GILBERT ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43,50-55 and 61 is/are pending in the application.
- 4a) Of the above claim(s) 2-22,25-43,50-55 and 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/1/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8,10,12. 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-43, 50-55 and 61 in Paper No. 6 filed 7-5-02, is acknowledged. The traversal is on the ground(s) that the inventions are not independent of each other, and thus there has been no showing that the groups are "distinct and independent."

This is not found persuasive because the *MPEP* § 803 states that restriction is proper if the inventions are *either* independent *or* distinct and if there is a burden on the Examiner if restriction is not required. As discussed in Paper No. 5, the search of the two inventions would require searches of different classes and subclasses and additionally would require searches of distinct subject matter in the non-patent literature.

Applicant's election of the species a pharmaceutical composition comprising copolymer 1 in a specified solid form such as a tablet as recited in Claim 24.

Applicant traverses said restriction on the grounds that a search and examination of all the species can be made without serious burden. However, it is noted that though a search of each of said species would be overlapping, it would not be coextensive, and as such would constitute an undue search burden.

The requirement is still deemed proper and is therefore made FINAL.

Claim 55 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claims 1 and 23-24 read on the elected species.

Since art was found on the elected species, claims 2-22, 25-43, 50-54 and 61, which read on the non-elected species, have been withdrawn from consideration.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

It is noted that Applicant filed an IDS and accompanying references on 7-8-02(Paper No.7). However, the 1449 form and said references are not able to be located by the examiner.

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Applicant is kindly requested to send a courtesy copy of said 1449 form and paper copies of the references listed therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO9830227, in view of US Patent 3,991,210 (Nov 1976).

'227 teaches a pharmaceutical composition comprising as an active ingredient a therapeutically effective amount of Copolymer 1 (glatimer acetate). '227 teaches a method of treating multiple sclerosis by oral administration of copolymer-1 through ingestion, and that when copolymer-1 is introduced orally it may be in solid form, and it may be mixed with pharmaceutically acceptable carrier.

'227 does not specifically teach that said carrier is microcrystalline cellulose.

'210 teaches that microcrystalline cellulose is a solid pharmaceutical carrier for solid compositions such as tablets (see entire patent especially column 3, last paragraph and lines 1-2 of column 4) and that tablets can be made in unit dosage forms adapted for oral administration (column 4, lines 30-35).

Therefore, one of skill who wanted to treat a patient with multiple sclerosis, would have been motivated to have made a solid form of a pharmaceutical composition comprising as an active ingredient, a therapeutically effective amount of Copolymer 1, as taught by '227, wherein said solid form was a tablet comprising microcrystalline cellulose as taught by '210, because '227 teaches that multiple sclerosis can be treated by oral administration of Copolymer 1, and because '210 teaches that tablets can be made for oral administration, and that microcrystalline cellulose is an acceptable solid pharmaceutical carrier for solid compositions such as tablets.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

No Claim is allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.,
Patent Examiner,
December 22, 2002


Patrick J. Nolan, Ph.D.,
Primary Patent Examiner
Group 1640